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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,043	02/04/2005	Paul Howley	23117	4403

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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,043	HOWLEY ET AL.	
	Examiner	Art Unit	
	Benjamin P. Blumel	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-60* is/are pending in the application.

4a) Of the above claim(s) *41-44, 46, 47 and 57-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-40,45,48-56 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4/6/07 & 2/4/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's amendments.

Election/Restrictions

This application contains claims 41-44, 46, 47 and 57-59 drawn to inventions nonelected with traverse in the reply filed on October 11, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments

Applicant's arguments filed April 6, 2007 and May 25, 2007 have been fully considered but they are not persuasive. See response below. In addition, applicants stated in the interview summary submitted on May 25, 2007 that the examiners (Examiner Blumel and Campell) "seemed to accept the argument that claims to such an invention would patentably distinguish over the cited prior art" as stated in page 11. Examiner Blumel wishes to reiterate that no acceptance of any claimed invention was implied since the examiners stated that patentable weight would only be considered based on the response and any amendments made in view of the prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Prior Rejection Maintained) Claims 32, 35, 36-40, 45, 50 and 52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Tartaglia et al. (US 6,004,777).

The claimed invention is drawn to a recombinant avipoxvirus that contains a host range gene of vaccinia virus or a homologue thereof, which results in an increased titer compared to a virus without the host range gene and an isolated avian cell containing the recombinant avipoxvirus. The avipoxvirus could be either a canarypoxvirus (CPV) or a fowlpoxvirus (FPV) and the host range genes could either be C18L, C17L, C7L, K1L, B4R, B23R or B24R. The recombinant avipoxvirus can also express heterologous gene, such as an antigen or a therapeutic compound, as part of a vaccine composition. The examiner acknowledges that the claimed product includes the limitation of propagation in avian cells.

Applicants argue that Tartaglia does not teach an increased titer of an avipoxvirus as a result of a vaccinia virus host range gene being inserted into the avipox genome. In response, even though Tartaglia et al. do not teach an increased titer of the recombinant avipoxvirus, the chimeric avipox/vaccinia virus of Tartaglia et al. (FPV or CPV with vaccinia E3L and/or K3L) inherently possesses this property since the specification of the instant application defines a homologue as "wherein the "homologue of the host range gene" has the biological function-of a host range gene" on page 5, lines 28-29. Therefore, the claimed invention recites vaccinia virus

host range homologues and disclose an immunological composition of recombinant poxviruses (FPV and CPV) that express heterologous antigens. Tartaglia et al. discuss the improved expression of heterologous antigens through the insertion of translation factors into the genome of recombinant poxviruses. The translation factors can be the open reading frames of: E3L, K3L or a homolog thereof. Tartaglia et al. teach that the preferred translation factors are the Vaccinia E3L and K3L, which can be inserted in combination or separately into the recombinant poxvirus genome. However, this limitation is not given any patentable weight since the claimed invention is drawn to a product and not a process of making/producing. Furthermore, the recitation of "as drug for effecting an immunological response in a living animal, including a human" in claim 40 is interpreted as an intended use and therefore will only be examined as the avipoxvirus of claim 32.

(New Rejection Necessitated By Amendments) Claims 45, 48-50, 52-56 rejected under 35 U.S.C. 102(b) as being anticipated by Cardona et al. (Virus Genes, 2001).

The claimed invention is drawn to an isolated avian cell, which contains recombinant avipoxviruses.

Cardona et al. teach chicken embryo fibroblasts and their use in tissue culture procedures. Even though Cardona et al. do not teach the claimed recombinant avipoxvirus being replicated in CEF cells that is irrelevant since the claimed invention is drawn to an isolated avian, not the virus. Furthermore, the presence of the recombinant avipoxvirus in the isolated avian cell does not alter the cell in such a way as to make it patentably distinct from the same isolated avian cell free from avipoxviruses.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33, 34 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. (US 6,004,777) as applied to claims 32 and 35-40 above, and further in view of Antoine et al. (Virology, 1998) and Fields et al. (Fields Virology 3rd Ed., 1996).

The claimed invention is drawn to a recombinant avipoxvirus that contains a host range gene of vaccinia virus or a homologue thereof, which results in an increased titer compared to a virus without the host range gene and an isolated avian cell containing the recombinant avipoxvirus. The avipoxvirus could be either a canarypoxvirus (CPV) or a fowlpoxvirus (FPV) and the host range genes could either be C18L, C17L, C7L, K1L, B4R, B23R or B24R. The recombinant avipoxvirus can also express heterologous gene, such as an antigen or a therapeutic

compound, as part of a vaccine composition. The examiner acknowledges that the claimed product includes the limitation of propagation in avian cells.

The teachings of Tartaglia et al. are discussed above, however Tartaglia et al. do not teach the host range genes of C17L, C18L, C7L, K1L, B4R, B23R or B24R from vaccinia virus.

Antoine et al. teaches the complete genome of the MVA virus and its comparison to other Orthopoxviruses. Antoine et al. identifies the hose range genes C17L, C18L, C7L, K1L, B4R, B23R or B24R at the open reading frames of 3L and 4L (C17L/B23R), 18L (C7L), 22L (K1L), 171R (B4R) and 190R (B23R). *See table 1.*

Fields et al. also teach the genome poxviruses and describe the various vaccinia virus genes based on a *Hind* III endonuclease mapping of the virus. Fields et al. indicate that C18L and C17L, B23R and B24R represent the same open reading frame (ORF) of vaccinia virus genes. *See page 2642, figure 5.*

It would have been obvious to one of ordinary skill in the art to modify the composition taught by Tartaglia et al. in order to generate an avipoxvirus with a vaccinia virus host range gene inserted into the avipoxvirus genome. One would have been motivated to do so, given the suggestion by Tartaglia et al. that either CPV or FPV can be modified by inserting the vaccinia virus E3L host range gene or a homologue thereof into either of the avipoxviruses genome in order to increase expression of heterologous genes. There would have been a reasonable expectation of success, given the knowledge that the vaccinia virus host range genes C17L, C18L, C7L, K1L, B4R, B23R and B24R were identified and sequence from MVA virus, the same virus utilized in the specification, prior to the claimed invention, as taught by Antoine et al., and also given the knowledge that C17, C18L and B23R, B24R represent the same ORF of

vaccinia virus, as taught by Fields et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48, 50 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that a vaccinia virus host range gene integrated into an avian host cell genome is required to practice the claimed invention because it is a necessary limitation for the success of the invention as stated in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the recombinant avian cell that stably expresses the host range gene. See 37 CFR 1.802. One cannot practice the claimed invention without possessing an avian cell with a vaccinia virus host range gene as part of the host cell genome. One cannot determine whether the recombinant host cell has the necessary characteristics without access to said host cell. Therefore, access to the recombinant avian cell is required to practice the invention. The specification does not provide a repeatable method for making the recombinant avian host cell without access to the recombinant avian host cell and it does not appear to be readily available material.

Deposit of the recombinant avian host cell in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed

by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:
(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claimed invention recites "said viral genome" on lines 5 and 8. However, it is unclear which viral genome, "said viral genome" is referring to since avipoxvirus and vaccinia virus are also disclosed in the claim.

Claim Objections

Claim 40 is objected to because of the following informalities: the claim recites "as drug for effecting an immunological response...". It is suggested that applicants amend the claim to recite "as **a** drug for effecting an immunological response...". Appropriate correction is required.

Summary

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin P Blumel/
Examiner
Art Unit 1648

ALI R. SALIMI
PRIMARY EXAMINER